

AMENDMENT AND RESPONSE UNDER 37 C.F.R §1.111

Application No. 10/653,027

Title: Tissue Connector Apparatus and Methods

REMARKS

Reconsideration and withdrawal of the claims rejections, in view of the amendments and arguments presented herein, is respectfully requested.

1, 3, 5, 6, and 8-35 are pending. Claims 4 and 7 have been cancelled without prejudice. Claim 1 has been amended to include the “suture” recited in now cancelled claim 7. No new matter has been added by way of these amendments.

35 U.S.C. §102 Rejections

Claims 1, 11, 12, 18 and 19 were rejected under 35 U.S.C. §102(b) as being anticipated by Sander (U.S. Patent No. 5,374,268). Although Applicant disagrees with assertion that Sander discloses a surgical fastener that is adapted to “assume” a loop configuration or that either anchoring member 14 corresponds to a flexible member as set forth in Applicant’s claim 1 as anchoring members 14 are not shown flexing, Applicant has amended claim 1 to expedite prosecution. Amended claim 1 recites that the flexible member comprises a suture and Sander clearly does not disclose or suggest this feature. Applicant further submits that previous claim 7, which recited that the flexible member comprises a suture, was not rejected under Sander.

Claims 11, 12, 18 and 19 depend directly or indirectly from independent claim 1 and therefore are not anticipated by Sander. These claims contain subject matter not disclosed in Sander as well. For example, Sander does not disclose an enlarged portion as set forth in dependent claim 19.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 102(a) rejection under Sander.

Claims 1, 28, 29, and 31-35 were rejected under 35 U.S.C. §102(e) as being anticipated by Bolduc et al (U.S. Patent No. 6,254,615) with reference to figures 12G and 12F.

Bolduc et al discloses a fastener or clip 192f in figures 12F and 12G. Clip 192f is a clip of unitary construction. It has end portions that form needle portions 220A and 220B and an intermediate section 222, which may include a loop 224. The intermediate section and needle end portions are part of the fastener and are shown integrally formed as a single unitary construction. Further, Applicant submits that the characterization in the Office Action that

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portion 224 is a clip is improper. The tissue is retained between needle portions 220A and 220B (see e.g., col. 17, lines 1-2) and not in loop 224. Loop 224 is part of the fastener and is there to enhance deflection of needle portions 220A and 220B (see e.g., col. 16, lines 64-65). Therefore, loop 224 does not correspond to a fastener, but merely a portion of a fastener and alone has no fastening function.

Regarding amended independent claim 1, as apparent from the foregoing, Bolduc et al does not disclose or suggest an assembly comprising (1) a fastener and (2) a flexible member and (3) two tissue piercing members, let alone a flexible member having one end portion that is “coupled” to one tissue piercing member or another end portion that is “coupled” to another tissue piercing member.

Element 192f of Bolduc et al corresponds to a fastener and nothing more. The needle end portions form part of the fastener. Further, there is no flexible member shown in addition to fastener 192f, let alone a flexible member coupled to tissue piercing members as noted above. Fastener 192f in Bolduc et al also is devoid of any flexible member that comprises a suture as recited in amended claim 1. Therefore, Bolduc et al does not anticipate claim 1 or claims 28, 29, 31, and 32, which depend directly or indirectly therefrom. The dependent claims also contain allowable subject matter.

Regarding independent claims 33-35, Bolduc et al does not disclose or suggest an assembly comprising (1) a fastener and (2) two tissue piercing members, let alone one tissue piercing member “coupled” to one end portion of the fastener or another tissue piercing member that is “coupled” to another end portion of the fastener.

Claims 33 and 34 also emphasize the separateness of the tissue piercing members with reference to them as being discrete. Bolduc et al clearly does not disclose or suggest discrete tissue piercing members. The tissue piercing members in Bolduc et al are part of a single fastener and are not individually separate and distinct elements.

Claim 35 describes the surgical fastener as comprising a surgical clip having an open configuration where the clip assumes a spiral configuration when in the closed configuration. As shown in FIG. 12G, clip 192f of Bolduc et al does not assume a spiral configuration when in a closed configuration. The end portions of the clip are not shown as getting progressively farther

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away from the central point of the clip as those portions revolve around that point. Although portions of the clip cross over one another, the clip does not assume a spiral configuration as claimed. Applicant further submits that the Applicant's clip can assume a spiral configuration when the clip is in a relaxed state and that a relaxed state can be achieved outside a patient's body. Therefore, the characterization in the Office Action of a relaxed state being in a patient's body is not understood.

Accordingly, Applicant submits that independent claims 1 and 33-35 as well as dependent claims 28, 29, 31 and 32 are not anticipated by Bolduc et al.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 102(e) rejection under Bolduc et al.

35 U.S.C. §103 Rejections

Claims 1, 3-5, 7, 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Northrup (U.S. Patent No. 5,972,024) in view of Krajicek (U.S. Patent No. 5,413,597). It was advanced that Northrup discloses a tissue connector assembly including first and second tissue piercing members 40, a surgical fastener 310 (figure 9) adapted to assume a loop configuration and having first and second end portions (i.e., one end of the fastener has two portions for receiving the piercing members and flexible members) with the first tissue piercing member being coupled to the first end portion and the second tissue piercing member being coupled to the second end portion, a flexible member 20 with a first end portion coupled to the tissue piercing member and a second portion having coupled to the first end portion of the fastener, a second flexible member 20 having a first end portion coupled to the second tissue piercing member and a second end portion coupled to the second end portion. It was then noted that Northrup does not disclose that the surgical fastener is an apparatus or an artificial implant, but advanced that it would have been obvious to apply an artificial surgical fastener in the apparatus of Northrup in view of Krajicek.

Contrary to the Examiner's assertion, Northrup does not disclose a tissue connector assembly having two tissue piercing elements and a surgical fastener. In the referenced figure 9, Northrup shows an end-to-end anastomosis being made using two separate tissue connector

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assemblies, each having a single suture 20, a single needle 40, and a single holding device 60. Neither of these tissue connector assemblies has two tissue piercing members as recited in independent claim 1 from which claims 3, 5-7, 9 and 10 depend either directly or indirectly.

Further, the assertion in the Office Action that element 310 (or element 320) in Northrup forms part of the claimed tissue connector assembly appears misplaced. Element 310 and 320 are structures such as vessels, which the two discrete tissue connector assemblies join. Neither of these structures form part of a tissue connector assembly. And it would be improper to construe the rejected claims as including body parts.

In view of the foregoing deficiencies in the Northrup, primary reference, a *prima facie* case of obviousness has not been established.

Applicant further submits that there is nothing in Krajicek that suggests adding a prosthesis to either of the tissue connectors of Northrup or how such an addition would provide the claimed assembly. Further, the Office Action does not explain how such a modification would be carried out, let alone why one would add a prosthesis to the surgical fastener of Northrup. For example, nothing in the Office Action explains how the end-to-end anastomosis method shown in Northrup's figure 9 would be carried out if one were to attach a prosthesis to one of the tissue connectors of Northrup. In column 5, lines 32-37, it states: "Once sutures 20 are appropriately placed, sutures 20 can be "parachuted" by pulling the respective vascular structures apart, in order to check for proper positioning and spacing of sutures 20 and/or holding devices 60. This also enables the surgeon to check for crosses, tangles, etc. in sutures 20 themselves."

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 3, 5, 9 and 10 under 35 U.S.C. §103(a) as being unpatentable over Northrup in view of Krajicek.

Claims 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Northrup (U.S. Patent No. 5,972,024) in view of Krajicek (U.S. Patent No. 5,413,597) and further in view of Pyka et al (U.S. Patent No. 5,002,563). Pyka does not make up for the noted deficiencies in Northrup and Krajicek. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

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Obviousness-type Double Patenting Rejections

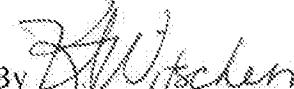
Claims 1 and 3-35 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-69 in co-pending application serial no. 10/208,405. Although Applicant does not necessarily agree with the claim summary set forth in the Office Action, a terminal disclaimer for co-pending application serial no. 10/208,405 is submitted herewith to expedite prosecution.

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned agent at 763-505-8418.

A request for a two (2) month extension of time under 37 C.F.R. 1.136(a) has been made with this Amendment. Please charge to Deposit Account No. 13-2546 the fee of \$490.00 which is required for the two-month extension of time. Please charge any additional required fees or credit any overpayment to Deposit Account No. 13-2546.

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